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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-20-0263]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Requirements for the Importation of Nonhuman Primates into the United States to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on December 6, 2019 to obtain comments from the public and affected agencies. CDC received six comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of

the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the

Attention: CDC Desk Officer, Office of Management and Budget, 725
17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806.
Provide written comments within 30 days of notice publication.

Proposed Project

Requirements for the Importation of Nonhuman Primates into the
United States (OMB Control No. 0920-0263, Exp. 08/31/2020) -
Revision - National Center for Emerging and Zoonotic Infectious
Diseases (NCEZID), Centers for Disease Control and Prevention
(CDC).

Background and Brief Description

Under 42 CFR 71.53, CDC collects information pertaining to
importers and imported nonhuman primates (NHP). This information
collection enables CDC to evaluate compliance with pre-arrival
of shipment notification requirements, to investigate the number
and species of imported nonhuman primates, and to determine if
adequate measures being taken for the prevention of exposure to
persons and animals during importation.

Since May 1990, CDC has monitored the arrival and/or
uncrating of certain shipments of non-human primates imported
into the United States. In February 2013, CDC promulgated two
regulations pertaining to the importation of nonhuman primates.
The first rule, Establishment of User Fees for Filovirus Testing

of Nonhuman Primate Liver Samples, outlines a process by which importers can send liver tissues to CDC from primates that die during importation from reasons other than trauma (2/12/2013, Vol.78, No. 29, p.9828). CDC performs these tests due to the absence of a private sector option. The second rule, Requirements for Importers of Nonhuman Primates, consolidates into 42 CFR 71.53 the requirements previously found in 42 CFR part 71.53 with those found in the Special Permit to Import Cynomolgus, African Green, or Rhesus Monkeys into the United States (2/15/2013, Vol. 78, No. 32 /p. 11522). It also rescinded the six-month special-permit requirements for cynomolgus, African green, and rhesus monkeys and extended the time period for registration/permit renewal from 180 days to two years, reducing much of the respondent burden. CDC feels these regulatory changes and reporting requirements balance the public health risks posed by the importation of nonhuman primates with the burden imposed on regulating their importation.

This information collection is designed to support real-time regulatory and monitoring activities, and the prevention of disease transmission from NHP to humans. Therefore, there is no standard reporting deadline or frequency. Respondents are only required to provide the information under the regulation if they seek to import nonhuman primates in the United States.

The CDC is requesting approval for a set of adjustments to the previously approved burden total for this information collection. The adjustments are as follows:

Adjustments:

Based on the number of registered importers processed by CDC, CDC is adjusting upward, two of the information collections within this submission:

- Nonhuman Primate Importer Recordkeeping and reporting requirements for importing NHPs: Notification of shipment arrival 71.53(n).
- Nonhuman Primate Importer Quarantine release 71.53(1).

Changes:

CDC is proposing a reformatting and changes to CDC 75.10A Registration Form for NHP Importation to clarify for respondents the information that should be submitted. This results in no changes in respondent burden.

CDC is adding the following information collections to delineate between specific information collections under the regulations at 42 CFR 71.53(m):

- Statements regarding the health of the nonhuman primates during travel and CDC quarantine (42 CFR 71.53(m) (no form)
- Statements, including necropsy reports, about the nonhuman primates upon their release from CDC quarantine. (42 CFR 71.53(m))

CDC is removing information collections, because CDC is not using the Partner Government Agency Message Set functionality within the Automated Commercial Environment:

- CDC Partner Government Agency Message Set for Importing Live Nonhuman Primates
- CDC Partner Government Agency Message Set for Importing Nonhuman Primate Products
- Documentation of Non-infectiousness 71.53(t)

OMB approval is requested for three years. The total number of hours requested for this information collection total 185, which is a decrease of 737 hours.

Estimated Annualized Burden Hours

Type of Respondent	Form Name/CFR Reference	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)
Nonhuman Primate Importer	CDC 75.10A Application for Registration as an Importer of Nonhuman Primates (New Importer)	1	1	10/60
Nonhuman Primate Importer	CDC 75.10A Application for Registration as an Importer of	12	1	10/60

	Nonhuman Primates (Re-Registration)			
Nonhuman Primate Importer	71.53(g) (1) (i ii) and (h) Documentation and Standard Operating Procedures (no form) (New Importer)	1	1	10
Nonhuman Primate Importer	71.53(g) (1) (i ii) and (h) Documentation and Standard Operating Procedures (no form) (Registered Importer)	12	1	30/60
Nonhuman Primate Importer	Recordkeeping and reporting requirements for importing NHPs: Notification of shipment arrival 71.53 (k), (n) (no form)	25	6	15/60
Nonhuman Primate Importer	Statements regarding the health of the nonhuman primates during travel and CDC quarantine (42 CFR 71.53(m) (no form)	25	6	15/60
Nonhuman Primate Importer	Statements, including necropsy reports, about the	25	3	15/60

	nonhuman primates upon their release from CDC quarantine. (42 CFR 71.53(m) (no form)			
Nonhuman Primate Importer	Quarantine release 71.53(l) (no form)	25	6	15/60
Nonhuman Primate Importer	71.53 (v) Form: Filovirus Diagnostic Specimen Submission Form for Non-human Primate Materials	10	10	20/60

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